

**RULE 63 (37 C.F.R. 1.63)**  
**INVENTORS DECLARATION FOR PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**MONITORING PATIENT COMPLIANCE AND BIOAVAILABILITY OF DRUGS BY DEPOTIZING BODY FLUIDS**

the specification of which (check applicable box(es)):

☐ is attached hereto  
☒ was filed on July 19, 2000 as U.S. Application Serial No. (Atty Dkt. No. 3673-3)  
☒ was filed as PCT International application No. PCT/BR99/00096 on 23 November 1999  
 and (if applicable to U.S. or PCT application) was amended on \_\_\_\_\_

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. 1.56. I hereby claim foreign priority benefits under 35 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed or, if no priority is claimed, before the filing date of this application:

Priority Foreign Application(s):

Application Number	Country	Day/Month/Year Filed
PI 9804648-9	Brazil	23 November 1998

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

Application Number	Date/Month/Year Filed
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I hereby claim the benefit under 35 U.S.C. 120/365 of all prior United States and PCT international applications listed above or below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior applications in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. 1.56 which occurred between the filing date of the prior applications and the national or PCT international filing date of this application:

Prior U.S./PCT Application(s):

Application Serial No.	Day/Month/Year Filed
PCT/BR99/00096	23 November 1999

Status: patented  
pending, abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. And on behalf of the owner(s) hereof, I hereby appoint NIXON & VANDERHYE P.C., 1100 North Glebe Rd., 8<sup>th</sup> Floor, Arlington, VA 22201-4714, telephone number (703) 816-4000 (to whom all communications are to be directed), and the following attorneys thereof (of the same address) individually and collectively owner's/owners' attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent: Arthur R. Crawford, 25327; Larry S. Nixon, 25640; Robert A. Vanderhye, 27076; James T. Hosmer, 30184; Robert W. Faris, 31352; Richard G. Besh, 22770; Mark E. Nusbaum, 32348; Michael J. Keenan, 32106; Bryan H. Davidson, 30251; Stanley C. Spooner, 27393; Leonard C. Mitchard, 29009; Duane M. Byers, 33363; Jeffrey H. Nelson, 30481; John R. Lastova, 33149; H. Warren Burnam, Jr., 29366; Thomas E. Byrne, 32205; Mary J. Wilson, 32955; J. Scott Davidson, 33489; Alan M. Kagen, 36178; Robert A. Molan, 29834; B. J. Sadoff, 36663; James D. Berquist, 34776; Updeep S. Gill, 37334; Michael J. Shea, 34725; Donald L. Jackson, 44090; Michelle N. Lester, 32331; Frank P. Presta, 19828; Joseph S. Presta, 35229; Joseph A. Rhoads, 37515. I also authorize Nixon & Vanderhye to delete any attorney names/numbers no longer with the firm and to act and rely solely on instructions directly communicated from the person, assignee, attorney, firm, or other organization sending instructions to Nixon & Vanderhye on behalf of the owner(s).

1-00 Inventor's Signature: Milton F. Ferreira

Inventor:

Milton  
(first)

F.  
(last)

FERREIRA  
(last)

Date: August 22, 2000

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2-00 Inventor's Signature: Vera Lucia Buify

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FOR ADDITIONAL INVENTORS, check box ☒ and attach sheet with same information and signature and date for each.

Applicant or Patentee: FERREIRA et al. Attorney's Dkt. No. 3673-3  
 Serial or Patent No.: \_\_\_\_\_  
 Filed or Issued: July 19, 2000  
 For: **MONITORING PATIENT COMPLIANCE AND BIOAVAILABILITY OF DRUGS BY DEPOTIZING BODY FLUIDS**

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS [37 CFR 1.9(f) and 1.27(c)] - SMALL BUSINESS CONCERN**

I hereby declare that I am

- ☐ the owner of the small business concern identified below:  
☒ an official of the small business concern empowered to act on behalf of the concern identified below:  
 NAME OF CONCERN FUNDACAO OSWALDO CRUZ - FIOCRUZ

ADDRESS OF CONCERN Avenida Brasil 4365, 21045-900, Manguinhos, Rio de Janeiro RJ Brasil

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled:

**MONITORING PATIENT COMPLIANCE AND BIOAVAILABILITY OF DRUGS BY DEPOTIZING BODY FLUIDS**

by inventors FERREIRA et al. described in

- ☐ the specification filed herewith.  
☒ application Serial No. 09/600,594, filed July 19, 2000  
☐ patent No. \_\_\_\_\_, issued \_\_\_\_\_

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor who could not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

Name \_\_\_\_\_  
 Address \_\_\_\_\_  
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Name \_\_\_\_\_  
 Address \_\_\_\_\_  
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application of patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. [37 CFR 1.28(b)]

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING X Eloi de Souza Garcia  
 TITLE OF PERSON OTHER THAN OWNER X President  
 ADDRESS OF PERSON SIGNING X Av. Brasil 4365, 21045-900, Manguinhos, RJ/BR  
 SIGNATURE X Eloi de Souza Garcia DATE X 23 August 2000

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3. Inventor's Signature: [Signature] Date: August 22, 2000  
Inventor: Eduardo W. BARROSO  
(first) (last)  
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4-00

4. Inventor's Signature: [Signature] Date: August 27, 2000  
Inventor: André L. GEMAL  
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FOR ADDITIONAL INVENTORS, check box ☐ and attach sheet with same information and signature and date for each.

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